Claims

1. An adjuvant composition comprising an immunostimulatory saponin fraction derived from the bark of Quillaja Saponaria Molina as a single HPLC peak and a sterol, with the proviso that when the adjuvant formulation comprises an ISCOM the saponin is QS21.

2. An adjuvant composition as claimed in claim 1 wherein the immunologically active saponin fraction is derived from the bark of Quillaja Saponaria Molina is at least 90% pure.

3. An adjuvant composition as claimed in any one of claim 1, wherein the immunologically active saponin fraction derived from the bark of Quillaja Saponaria Molina is QS21.

4. An adjuvant composition as claimed in claim 1 wherein the sterol is in excess weight for weight to the immunologically active saponin fraction.

5. An adjuvant composition as claimed in any one of claim 1 wherein the ratio of saponin:sterol is from 1:100 to 1:1 (w/w).

6. An adjuvant composition as claimed in claim 5 wherein the ratio of saponin:sterol is at least 1:2 (w/w).

7. An adjuvant composition as claimed in claim 6, wherein the ratio of saponin:sterol is 1:5 (w/w).

8. An adjuvant composition as claimed in claim 1, wherein the immunologically active saponin fraction derived from the bark of Quillaja Saponaria Molina is QS17.

9. An adjuvant composition as claimed in claim 1, wherein the sterol is cholesterol.

10. An adjuvant composition as claimed in claim 1, wherein the adjuvant composition is in the form of a vesicle.

11. An adjuvant composition as claimed in claim 10, wherein the adjuvant composition is in the form of a liposome.

12. An adjuvant composition as claimed in claim 11, wherein the adjuvant composition is in the form of a small unilamellar liposome.

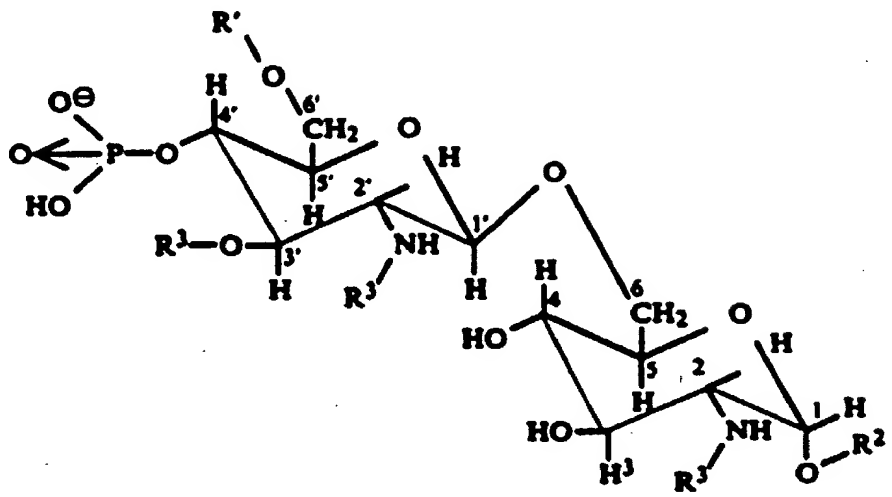
13. An adjuvant composition as claimed in claim 10, wherein the adjuvant composition further comprises a phospholipid.

14. An adjuvant composition as claimed in claim 13, wherein the phospholipid is dioleoyl phosphatidylcholine.

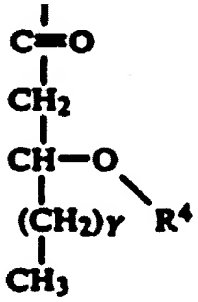
15. An adjuvant composition comprising a saponin, a sterol, and a derivative of LPS.

16. An adjuvant composition as claimed in claim 15, wherein the LPS derivative is present in a lipid bilayer membrane.

17. An adjuvant composition as claimed in claim 15, wherein the derivative of LPS is a purified or synthetic lipid A of the following formula:



wherein R2 may be H or PO3H2; R3 may be an acyl chain or β-hydroxymyristoyl or a 3-acyloxyacyl residue having the formula:



and wherein X and Y have a value of from 0 up to about 20.

18. An adjuvant composition as claimed in claim 17, wherein the LPS derivative is 3-O-deacylated monophosphoryl lipid A.

19. An adjuvant composition comprising QS21, 3D-MPL and cholesterol.

20. An adjuvant formulation comprising a purified and stable QS21 saponin which is substantially devoid of hydrolysed QS21

21. An adjuvant formulation comprising 3D-MPL and a liposome, wherein the 3D-MPL is present in the lipid bilayer membrane.

22. An adjuvant composition as claimed in any one of claims 1 to 21, wherein the composition further comprises a carrier.

23. An adjuvant composition as claimed in claim 22, wherein the carrier is an oil in water emulsion or a metallic salt particle.

24. An adjuvant composition comprising a saponin, a sterol and a metallic salt particle.

25. An adjuvant composition as claimed in claim 24, wherein the metallic salt particle is aluminium hydroxide or aluminium phosphate.

26. An adjuvant composition as claimed in claim 24, wherein the saponin is QS21.

27. An immunogenic composition comprising an adjuvant composition as claimed in any one of claims 1 to 21, further comprising an antigen or antigenic composition.

28. An immunogenic composition comprising an adjuvant composition as claimed in claim 22, further comprising an antigen or antigenic composition.

29. A vaccine composition as claimed in any one of claims 1 to 21, further comprising an antigen or antigenic composition.

30. A vaccine composition as claimed in claim 22, further comprising an antigen or antigenic composition.

31. A vaccine as claimed in claim 29, wherein the antigen is derived from any of Human Immunodeficiency Virus, Feline Immunodeficiency Virus, Varicella Zoster virus, Herpes Simplex Virus type 1, Herpes Simplex virus type 2, Human cytomegalovirus, Hepatitis A, B, C or E, Respiratory Syncytial virus, human papilloma virus, Influenza virus, Hib, Meningitis virus, Salmonella, Neisseria, Borrelia, Chlamydia, Bordetella, Plasmodium or Toxoplasma.

32. A vaccine as claimed in claim 30, wherein the antigen is derived from any of Human Immunodeficiency Virus, Feline Immunodeficiency Virus, Varicella Zoster virus, Herpes Simplex Virus type 1, Herpes Simplex virus type 2, Human cytomegalovirus, Hepatitis A, B, C or E, Respiratory Syncytial virus, human papilloma virus, Influenza virus, Hib, Meningitis virus, Salmonella, Neisseria, Borrelia, Chlamydia, Bordetella, Plasmodium or Toxoplasma.

33. A vaccine as claimed in claim 29 wherein the antigen is a tumour antigen.

34. A vaccine as claimed in claim 30 wherein the antigen is a tumour antigen.

35. A method of treating a mammal suffering from or susceptible to a pathogenic infection comprising the administration of a safe and effective amount of a composition as claimed in claim 27.

36. A method of treating a mammal suffering from or susceptible to a pathogenic infection comprising the administration of a safe and effective amount of a composition as claimed in claim 28.

37. A method of treating a mammal suffering from or susceptible to a pathogenic infection comprising the administration of a safe and effective amount of a composition as claimed in claim 29.

38. A method of treating a mammal suffering from or susceptible to a pathogenic infection comprising the administration of a safe and effective amount of a composition as claimed in claim 30.

39. A method of treating a mammal suffering from cancer comprising the administration of a safe and effective amount of a composition as claimed in claim 27.

40. A method of treating a mammal suffering from cancer comprising the administration of a safe and effective amount of a composition as claimed in claim 28.

41. A method of treating a mammal suffering from cancer comprising the administration of a safe and effective amount of a composition as claimed in claim 29.

42. A method of treating a mammal suffering from cancer comprising the administration of a safe and effective amount of a composition as claimed in claim 30.

43. A process for making a vaccine composition as claimed in claim 29, comprising admixing an immunologically active saponin fraction and cholesterol with an antigen or antigenic composition.

44. A process for making a vaccine composition as claimed in claim 30, comprising admixing an immunologically active saponin fraction and cholesterol with an antigen or antigenic composition.

45. A method of inducing CTL responses in a mammal comprising administering a vaccine composition as claimed in claim 29.

46. A method of inducing CTL responses in a mammal comprising administering a vaccine composition as claimed in claim 30.

47. A method of reducing the reactogenicity of QS21 containing adjuvant formulations, by the addition of excess sterol to the adjuvant formulation (weight/weight).

48. A method of stabilising QS21 against alkali mediated hydrolysis in QS21 containing adjuvant formulations, by the addition of excess sterol to the adjuvant formulation (weight/weight).

49. A process for the manufacture of an adjuvant formulation comprising making small unilamellar liposomes (SUV) comprising a sterol such as cholesterol, followed by the admixture of a saponin.